52.004-4000 'Reporting of Contractor Manpower Data Elements' (Jan 2001) (USAMRAA)

(a) - Scope. The following sets forth contractual requirements for reporting of contractor labor work year equivalents (also called Contractor Man-year Equivalents (CMEs) in support of the Army, pursuant to 10 U.S.C. 129a, 10 U.S.C. 2461(g), Section 343 of P.L. 106-65, and 32 CFR 668. Reporting shall be accomplished electronically by direct contractor submission to the secure Army Web Site: https://contractormanpower.us.army.mil. Information on the background, purposes, and significance of this reporting requirement, and the 32 CFR 668 Final Rule as published in the Federal Register, can be found at this Web Site. In addition, a Help Desk function, detailed instructions on what and how to report, FAQs, and a site demonstration are available. The Army's objective is to collect as much significant CME data as possible to allow accurate reporting to Congress and for effective Army planning. The reporting data elements should not be viewed as an "all or nothing" requirement. Even partial reporting, e.g., direct labor hours, appropriation data, place of performance, Army, customer, etc., will be helpful.

(b) - Applicability. This reporting requirement applies to services covered by Federal Supply Class or Service codes for "Research and Development and "Other Services and Construction" Report submissions shall not contain classified information. (Also see "Exemptions" at (d) below.)

(c) - Requirements. The contractor is required to report the following contractor manpower information, associated with performance of this contract action in support of Army requirements, for all covered contracts, to the Office, Assistant Secretary of the Army (Manpower and Reserve Affairs) (ASA(M&RA)), using the secure Army data collection web-site at https://contractormanpower.us.army.mil '(Other information requirements associated-with the manpower data collection (contract and task or delivery, order numbers; appropriation data and amounts; total estimated value of contract; federal supply class or service code; major Army organizational element receiving or reviewing work; beginning and ending date for reporting period; place of performance; name, address, and point of contract for contractor; etc.) are specified and explained at the web site.

(1) Labor Hours. Composite direct labor hours and the value of those hours. Composite indirect labor hours associated with the reported direct hours, and, the value of those indirect labor hours plus compensation related costs for direct labor hours ordinarily included in the indirect pools'

(2) Rates. Alternatively, contractors may report two distinct, relevant (annualized) composite or average indirect labor rates in lieu of raw indirect labor hours and the value of those indirect hours. Such rates shall be annualized average estimates for the reporting contractor and need not be developed for each reporting period. Either method chosen should be consistently reported.

(d) Exemption(s). If the contractor is unable to comply with these reporting requirements without creating a whole new cost allocation system or system of records (such as a payroll accounting system), or due to similar insurmountable practical or economic reasons, the contractor may claim an exemption to at least a portion of the reporting requirement by certifying in writing to the contracting officer the clear underlying reason(s) for exemption from the specified report data element(s), *and* further certifying that they do not otherwise have to provide the exempted information, in any form, to the United States Government. The "self-exemption" will, apply to all contract actions involving the contractor and will be reviewed and approved by the Deputy Assistant Secretary of the Army (Procurement), in coordination with the Deputy Assistant Secretary of the Army (Force Management and Resources), whose decision is final in this matter.

(e) Uses and Safeguarding of Information. The information submitted will be treated as contractor proprietary information when associated with a contractor name or contract number.

(f) Subcontract Data. The contractor shall ensure that all reportable subcontract data is timely reported to the data collection web site (citing this contract/order

number). At the discretion of the prime contractor, this reporting may be done directly by subcontractors to the data collection site; or by the prime contractor after consolidating and rationalizing-all significant data from their subcontractors.

(g) Report schedule. The contractor is required to report the required information to the ASA(M&RA) data collection web site generally contemporaneous with submission of a request for payment (for example, voucher, invoice, or request for progress payment), but not less frequently than quarterly, retroactive to October 1, 1999, or the start of the contract/order, whichever is later. Deviation from this schedule requires approval of the contracting officer.

(h) Reporting Flexibility. Contractors are encouraged to communicate with the Help Desk identified at the data collection web site to resolve reporting difficulties. The web site reporting pages include a "Remarks" field to accommodate non-standard data entries if needed to facilitate simplified reporting and to -minimize reporting burdens arising out of unique circumstances. Changes to facilitate reporting may be authorized by the contracting officer or the Help Desk (under HQDA policy direction and oversight).

Compensation** costs **are defined in** the **reporting instructions at the Army Web Site.

USAMRAA 52.035-4037 RDS (RDTE DILUTE SOLUTIONS)(NOVEMBER 2000)(USAMRAA)

A. The Contractor shall operate in a safe environment, with properly safe equipment and procedures. This means that, at a minimum, the Contractor shall satisfy the RDS-RDTE Dilute Solutions Standard located at http://www-usamraa.army.mil/regulatoryinfo.htm

B. All RDS disposal shall be addressed prior to expiration of the contract.

C. Requests for RDS shall be provided, in writing, to the Chief, Safety & Chemical Operations Officer at:

Commander
U.S. Army Medical Research Institute of
Chemical Defense
3100 Ricketts Point Road
ATTN: MCMR-UV-RS
Aberdeen Proving Ground, MD 21010-5400
(410) 436-4433 and fax: (410) 436-3004

with a copy furnished to the Contracting Officer at:

Director
U.S. Army Medical Research
Acquisition Activity
820 Chandler Street
ATTN: MCMR-AAA-( )
Fort Detrick, MD 21702-5014
(301) 619-( )

and the Contracting Officer's Representative (COR) at:

(fill in)

and shall furnish the following information:

Name of the Principal Investigator:
Name(s) and phone number(s) of custodian(s):
Shipment Address:
Contract Number:
RDS, Concentration, Amount, Diluent (if applicable),
and Specific Activity (if applicable)

End of Clause

USAMRAA 52.037-4000 CONTRACTOR IDENTIFICATION (Jan 2001)(USAMRAA)

When contractor personnel perform the services required in this contract on a government installation they are required to possess and wear an identification badge which displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, or working in situations where their actions could be construed as official Government acts.

USAMRAA 52.009-4004 **ORGANIZATIONAL AND CONSULTANT CONFLICTS OF INTEREST (MAR 1999) (USAMRAA)**

a. It is recognized by the parties hereto that the effort performed by the contractor under this contract is of a nature that it creates a potential organizational conflict of interest as is contemplated under the FAR Subpart 9.5.

b. In the performance of this contract, the contractor may have access to data which is procurement sensitive or is proprietary to other companies, Government consultants or advisors, or the Government. The contractor agrees that he will not utilize such procurement sensitive or proprietary data in performance of future competitive contracts, for studies in the same field, procured either through sealed bids or competitive negotiations. The contractor further agrees not to act as a subcontractor or consultant to any other prime contractor or subcontractor seeking to utilize such data.

c. The contractor will include the provisions of paragraphs a and b in every first tier subcontract for performance of any portion of this requirement.

d. This clause shall have effect from to .

USAMRAA 52.012-4001 **LEVEL OF EFFORT (MAR 1999) (USAMRAA)**

a. The level of effort shall be:

Personnel Category	Manhours	Period of Performance

Make sure your entries are lined up under the headings correctly.

USAMRAA 52.012-4008 **CONTRACT PERIOD (MAR 1999) (USAMRAA)**

The contract period is from to

USAMRAA 52.015-4003 **REPRESENTATIONS AND CERTIFICATIONS (MAR 1999) (USAMRAA)**

The representations, certifications, and other statements submitted by the contractor, dated , are incorporated herein by reference.

USAMRAA 52.016-4001 **TASK/DELIVERY ORDERS (MAR 1999) (USAMRAA)**

a. The contractor shall perform in accordance with the contract schedule and as called for by orders issued in accordance with this clause.

b. The SF 1155 or 1449 will be used to issue task assignments and to signify Contracting Officer notification to commence work under the individual task orders. The contractor shall not proceed with the task until notification is received from the Contracting Officer.

c. The task/delivery orders, and modifications to task/delivery orders, will be numbered by the issuing office. Modifications to the task/delivery orders will be designated by the modification number and contain the original task order number.

d. The contractor shall identify all correspondence,
reports, drawings, and other pertinent papers in connection with the contract by imprinting thereon the task/delivery order and the contract number, plus any other references furnished by the Contracting Officer.

e. The total of all completed and outstanding Task/Delivery Orders will at no time exceed the current amount obligated.

f. The Competition Advocate for the U.S. Army Medical Research Materiel Command, Fort Detrick, Maryland has been designated as the Ombudsman for this contract. (applicable to multiple award contracts only)

g. Procedures:

(1) Prior to issuance of a Task/Delivery Order and upon definition of the Government requirement, the Contracting Officer will, in writing, issue to the contractor a Task/Delivery Order Request for Proposal (RFP) which will designate a preferred Task/Delivery Order type.

(2) The contractor shall submit five (5) copies of the following in writing, by a date mutually agreed upon but no later than working days after receipt of the RFP:

a. Technical proposal (or Task Execution Plan (TEP)) which sets forth the contractor's understanding of the requirement, performance schedule, staffing plan, and level of effort required. The technical proposal/TEP should also address other documentation required by the Government to perform the task or any specific issues raised in the RFP.

b. Cost proposal which sets forth all costs associated with furnishing the required services, including cost or price data.

Note: If longer than days will be required, the contractor shall provide justification to the Contracting Officer by telephone as soon as possible after receipt of a task assignment.

The contractor's technical proposal/TEP shall be consistent with Section C and the technical and cost proposals incorporated into the contract. The contractor shall also identify any necessary differences between the technical proposal/TEP and the technical and business proposals incorporated into the contract.

(3) Upon receipt of the contractor's proposal, the Government will proceed to evaluate the same, subsequent to which negotiations will take place between the Contracting Officer and the contractor. The contractor is expressly forbidden from discussing with the Contracting Officer's Representative (COR), or any other Government technical personnel, any aspects of any pending Task/Delivery Orders absent expressed written permission from the Contracting Officer to that effect.

(4) Following the conclusion of negotiations, the Contracting Officer will issue a fully executed Task/Delivery Order, containing all agreed-to terms and conditions, specifying the task to be performed, special reporting requirements and a firm-fixed price amount.

(5) In the event that the parties fail to agree on Task Order type, price, costs and/or fixed fee or profit for any Task Order hereunder, the Contracting Officer may render a unilateral written decision as to what type of Task Order and what level of price or costs and/or fee/profit is reasonable under the circumstances for the services required pursuant to the Task Order, and will subsequently unilaterally issue the Task Order in accordance with that decision. Said decision shall constitute a decision rendered concerning a question of fact within the meaning of and governed by the terms of FAR Clause 52.233-1 in Section I of this contract.

USAMRAA 52.016-4001 ALT I **TASK/DELIVERY ORDERS -ALTERNATE I (MAR 1999) (USAMRAA)**

a. The contractor shall perform in accordance with the contract schedule and as called for by orders issued in accordance with this clause.

b. The SF 1155 or 1449 will be used to issue task assignments and to signify Contracting Officer notification to commence work under the individual task orders. The contractor shall not proceed with the task until notification is received from the Contracting Officer.

c. The task/delivery orders, and modifications to task/delivery orders, will be numbered by the issuing office. Modifications to the task/delivery orders will be designated by the modification number and contain the original task order number.

d. The contractor shall identify all correspondence,
reports, drawings, and other pertinent papers in connection with the contract by imprinting thereon the task/delivery order and the contract number, plus any other references furnished by the Contracting Officer.

e. The total of all completed and outstanding Task/Delivery Orders will at no time exceed the current amount obligated.

f. The Competition Advocate for the U.S. Army Medical Research Materiel Command, Fort Detrick, Maryland has been designated as the Ombudsman for this contract. (applicable to multiple award contracts only)

g. Procedures:

(1) Prior to issuance of a Task/Delivery Order and upon definition of the Government requirement, the Contracting Officer will, in writing, issue to the contractor a Task/Delivery Order Request for Proposal (RFP) which will designate a preferred Task/Delivery Order type.

(2) Where the level of effort identified by the Government is not sufficient to accomplish the task assigned or if the contractor determines that the task may expose the contractor to unacceptable hazards and/or risks, the contractor shall promptly notify the Contracting Officer of the problems encountered. Notwithstanding any other provisions, the unacceptable portion of any task order shall be resolved to both the Government's and the contractor's mutual satisfaction prior to commencement of work in these areas.

(3) The contractor shall submit five (5) copies of the following in writing, by a date mutually agreed upon but no later than working days after receipt of the RFP:

a. Technical proposal (or Task Execution Plan (TEP)) which sets forth the contractor's understanding of the requirement, performance schedule, staffing plan, and level of effort required. The technical proposal/TEP should also address other documentation required by the Government to perform the task or any specific issues raised in the RFP.

b. Cost proposal which sets forth all costs associated with furnishing the required services, including cost or price data.

Note: If longer than days will be required, the contractor shall provide justification to the Contracting Officer by telephone as soon as possible after receipt of a task assignment.

The contractor's technical proposal/TEP shall be consistent with Section C and the technical and cost proposals incorporated into the contract. The contractor shall also identify any necessary differences between the technical proposal/TEP and the technical and business proposals incorporated into the contract.

(4) Upon receipt of the contractor's proposal, the Government will proceed to evaluate the same, subsequent to which negotiations will take place between the Contracting Officer and the contractor. The contractor is expressly forbidden from discussing with the Contracting Officer's Representative (COR), or any other Government technical

personnel, any aspects of any pending Task/Delivery Orders absent expressed written permission from the Contracting Officer to that effect.

(5) Upon approval of the contractor's proposal, written authorization will be provided to initiate the study. Each separate study must have institution review approval. The contractor shall begin work on the approved task no later than 60 days following receipt of written authorization to initiate the study. The contractor agrees to initiate the study sooner than 60 days after receiving written authorization if effort of the required staff is available to devote to the task order. It is estimated that at least 60 days may be required to obtain both contractor's IRB approval and the Government's human use approval. Both parties agree to obtain approvals as expeditiously as possible after a requirement has been identified.

(6) Following the conclusion of negotiations, the Contracting Officer will issue a fully executed Task/Delivery Order, containing all agreed-to terms and conditions, specifying the task to be performed, technical contact for the particular study involved, special reporting requirements and a firm-fixed price amount.

(7) In the event that the parties fail to agree on Task Order type, price, costs and/or fixed fee or profit for any Task Order hereunder, the Contracting Officer may render a unilateral written decision as to what type of Task Order and what level of price or costs and/or fee/profit is reasonable under the circumstances for the services required pursuant to the Task Order, and will subsequently unilaterally issue the Task Order in accordance with that decision. Said decision shall constitute a decision rendered concerning a question of fact within the meaning of and governed by the terms of FAR Clause 52.233-1 in Section I of this contract.

USAMRAA 52.016-4001 ALT II **TASK/DELIVERY ORDERS - ALTERNATE II (MAR 1999) (USAMRAA)**

a. The contractor shall perform in accordance with the contract schedule and as called for by orders issued in accordance with this clause.

b. The SF 1155 or 1449 will be used to issue task assignments and to signify Contracting Officer notification to commence work under the individual task orders. The contractor shall not proceed with the task until notification is received from the Contracting Officer.

c. The task/delivery orders, and modifications to task/delivery orders, will be numbered by the issuing office. Modifications to the task/delivery orders will be designated by the modification number and contain the original task order number.

d. The contractor shall identify all correspondence,
reports, drawings, and other pertinent papers in connection with the contract by imprinting thereon the task/delivery order and the contract number, plus any other references furnished by the Contracting Officer.

e. The total of all completed and outstanding Task/Delivery Orders will at no time exceed the current amount obligated.

f. The Competition Advocate for the U.S. Army Medical Research Materiel Command, Fort Detrick, Maryland has been designated as the Ombudsman for this contract. (applicable to multiple award contracts only)

g. Procedures:

(1) Prior to issuance of a Task/Delivery Order and upon definition of the Government requirement, the Contracting Officer will, in writing, issue to the contractor a Task/Delivery Order Request for Proposal (RFP) which will designate a preferred Task/Delivery Order type.

(2) The contractor shall submit five (5) copies of the following in writing, by a date mutually agreed upon but no later than working days after receipt of the RFP:

a. Technical proposal (or Task Execution Plan (TEP)) which sets forth the contractor's understanding of the requirement, performance schedule, staffing plan, and level of effort required. The technical proposal/TEP should also address other documentation required by the Government to perform the task or any specific issues raised in the RFP.

b. Cost proposal which sets forth all costs associated with furnishing the required services, including cost or price data.

Note: If longer than days will be required, the contractor shall provide justification to the Contracting Officer by telephone as soon as possible after receipt of a task assignment.

The contractor's technical proposal/TEP shall be consistent with Section C and the technical and cost proposals incorporated into the contract. The contractor shall also identify any necessary differences between the technical proposal/TEP and the technical and business proposals incorporated into the contract.

(3) Upon receipt of the contractor's proposal, the Government will proceed to evaluate the same, subsequent to which negotiations will take place between the Contracting Officer and the contractor. The contractor is expressly forbidden from discussing with the Contracting Officer's Representative (COR), or any other Government technical personnel, any aspects of any pending Task/Delivery Orders absent expressed written permission from the Contracting Officer to that effect.

(4) Following the conclusion of negotiations, the Contracting Officer will issue a fully executed Task/Delivery Order, containing all agreed-to terms and conditions, specifying the task to be performed, special reporting

requirements and total estimated cost and fixed fee. The contractor shall in no event exceed the total estimated cost of the Task/Delivery Order (see FAR 52.232-20 and 52.232-22)

Whenever it appears to the contractor that the actual cost to complete any task may exceed the estimated cost of such task, the contractor shall immediately, and in no event later than the incurrence of 75% of the estimated task cost, notify the Contracting Officer in writing and furnish a revised estimate for the completion of the task. The contractor shall not incur costs to perform work under any specific task in excess of the cost estimate authorized for the task until the Contracting Officer notifies the contractor in writing that such amount has been increased. Issuance of a task order is not authorization for the contractor to incur costs in excess of the funds obligated to-date under the contract.

(5) In the event that the parties fail to agree on Task Order type, price, costs and/or fixed fee or profit for any Task Order hereunder, the Contracting Officer may render a unilateral written decision as to what type of Task Order and what level of price or costs and/or fee/profit is reasonable under the circumstances for the services required pursuant to the Task Order, and will subsequently unilaterally issue the Task Order in accordance with that decision. Said decision shall constitute a decision rendered concerning a question of fact within the meaning of and governed by the terms of FAR Clause 52.233-1 in Section I of this contract.

USAMRAA 52.016-4001 ALT III **TASK/DELIVERY ORDERS - ALTERNATE III (MAR 1999) (USAMRAA)**

a. The contractor shall perform in accordance with the contract schedule and as called for by orders issued in accordance with this clause.

b. The SF 1155 or 1449 will be used to issue task assignments and to signify Contracting Officer notification to commence work under the individual task orders. The contractor shall not proceed with the task until notification is received from the Contracting Officer.

c. The task/delivery orders, and modifications to task/delivery orders, will be numbered by the issuing office. Modifications to the task/delivery orders will be designated by the modification number and contain the original task order number.

d. The contractor shall identify all correspondence,
reports, drawings, and other pertinent papers in connection with the contract by imprinting thereon the task/delivery order and the contract number, plus any other references furnished by the Contracting Officer.

e. The total of all completed and outstanding Task/Delivery Orders will at no time exceed the current amount obligated.

f. The Competition Advocate for the U.S. Army Medical Research Materiel Command, Fort Detrick, Maryland has been designated as the Ombudsman for this contract. (applicable to multiple award contracts only)

g. Procedures:

(1) Prior to issuance of a Task/Delivery Order and upon definition of the Government requirement, the Contracting Officer will, in writing, issue to the contractor a Task/Delivery Order Request for Proposal (RFP) which will designate a preferred Task/Delivery Order type.

(2) Where the level of effort identified by the Government is not sufficient to accomplish the task assigned or if the contractor determines that the task may expose the contractor to unacceptable hazards and/or risks, the contractor shall promptly notify the Contracting Officer of the problems encountered. Notwithstanding any other provisions, the unacceptable portion of any task order shall be resolved to both the Government's and the contractor's mutual satisfaction prior to commencement of work in these areas.

(3) The contractor shall submit five (5) copies of the following in writing, by a date mutually agreed upon but no later than working days after receipt of the RFP:

a. Technical proposal (or Task Execution Plan (TEP)) which sets forth the contractor's understanding of the requirement, performance schedule, staffing plan, and level of effort required. The technical proposal/TEP should also address other documentation required by the Government to perform the task or any specific issues raised in the RFP.

b. Cost proposal which sets forth all costs associated with furnishing the required services, including cost or price data.

Note: If longer than days will be required, the contractor shall provide justification to the Contracting Officer by telephone as soon as possible after receipt of a task assignment.

The contractor's technical proposal/TEP shall be consistent with Section C and the technical and cost proposals incorporated into the contract. The contractor shall also identify any necessary differences between the technical proposal/TEP and the technical and business proposals incorporated into the contract.

(4) Upon receipt of the contractor's proposal, the Government will proceed to evaluate the same, subsequent to which negotiations will take place between the Contracting Officer and the contractor. The contractor is expressly forbidden from discussing with the Contracting Officer's Representative (COR), or any other Government technical

personnel, any aspects of any pending Task/Delivery Orders absent expressed written permission from the Contracting Officer to that effect.

(5) Upon approval of the contractor's proposal, written authorization will be provided to initiate the study. Each separate study must have institution review approval. The contractor shall begin work on the approved task no later than 60 days following receipt of written authorization to initiate the study. The contractor agrees to initiate the study sooner than 60 days after receiving written authorization if effort of the required staff is available to devote to the task order. It is estimated that at least 60 days may be required to obtain both contractor's IRB approval and the Government's human use approval. Both parties agree to obtain approvals as expeditiously as possible after a requirement has been identified.

(6) Following the conclusion of negotiations, the Contracting Officer will issue a fully executed Task/Delivery Order, containing all agreed-to terms and conditions, specifying the task to be performed, technical contact for the particular study involved, special reporting requirements and total estimated cost and fixed fee. The contractor shall in no event exceed the total estimated cost of the Task/Delivery Order (see FAR 52.232-20 and 52.232-22)

Whenever it appears to the contractor that the actual cost to complete any task may exceed the estimated cost of such task, the contractor shall immediately, and in no event later than l4 calendar days prior to the time that the actual costs for which the contractor requires reimbursement will equal the estimated cost, notify the Contracting Officer in writing and furnish a revised estimate for the completion of the task. The contractor shall not incur costs to perform work under any specific task in excess of the cost estimate authorized for the task until the Contracting Officer notifies the contractor in writing that such amount has been increased. Issuance of a task order is not authorization for the contractor to incur costs in excess of the funds obligated to-date under the contract.

(7) In the event that the parties fail to agree on Task Order type, price, costs and/or fixed fee or profit for any Task Order hereunder, the Contracting Officer may render a unilateral written decision as to what type of Task Order and what level of price or costs and/or fee/profit is reasonable under the circumstances for the services required pursuant to the Task Order, and will subsequently unilaterally issue the Task Order in accordance with that decision. Said decision shall constitute a decision rendered concerning a question of fact within the meaning of and governed by the terms of FAR Clause 52.233-1 in Section I of this contract.

USAMRAA 52.016-4006 **CONTRACT CEILING (MAR 1999) (USAMRAA)**

The ceiling price of this contract is $. The contractor agrees that the work performed under this contract shall be accomplished within the specified ceiling price. Unless and until the Contracting Officer has notified the contractor in writing that the ceiling price has been increased and the amount of the increase, any costs incurred in excess of the ceiling price shall be borne by the contractor. The contractor's attention is directed to Section of this contract, entitled "Task/Delivery Orders". Contractor entitlement to the monies specified as the contract ceiling is derived solely from the issuance and successful performance of task/ delivery orders against that ceiling amount.

USAMRAA 52.023-4011 **SAFETY PROGRAM PLAN (MAR 1999) (USAMRAA)**

Each of the applicable items below must be addressed in a proposal appendix entitled "Safety Program Plan" and must be prepared specifically for the proposal. Each section should be operation/research specific and addressed in order.

Institutional safety manuals may be referenced; however, do not send copies of Facility Safety Plan (FSP) or Standard Operating Procedures (SOPs). A list of program contents with a brief description of each item (maximum 3 pages) is acceptable. If not applicable, so state. Provide a website address, if available, for additional safety and occupational health information.

Those items that do not apply to the proposed research will be labeled as "not applicable" or "N/A."

1. Affirmation of Safety

The PI (recipient) shall submit the following paragraph as affirmation that a safety program is in place and in accordance with all applicable regulations.

(Recipient name) affirms that there is an existing safety program that is an accordance with appropriate Federal, State, and Local regulations, as required by the Occupational Safety and Health Act; that hazards have been identified, eliminated, and/or controlled; and that research may be performed safely under laboratory conditions. (Recipient name) shall be held responsible and liable for inaccuracies of the information provided, failure to implement an effective safety and occupational health program, and/or adverse conditions that may result from the failure of the recipient to identify hazard information.

_____
Signature of Recipient, Date

2. Research Operations/Standard Operating Procedures (SOPs)

Safety procedures relating to the research operation. These should include but are not limited to the following: description of safety procedures for performing the protocol; description of any special skills, training, and SOPs to assure safe research operations (Safety Committee, HAZCOM, Bloodborne Pathogen, and Chemical Hygiene, etc.); and description of medical surveillance and support.

3. Facility Equipment and Description

This should include a description of any biological safety cabinets, ventilation system employed, and personal protective equipment.

4. Hazard Analysis

Include a description of each hazard identified, hazard analysis based on maximum credible event, and plan to minimize or eliminate hazards (infection, toxic substance, and biological hazards).

5. Radioactive Materials

If radioactive materials are used, the materials and the disposal method should be identified. A copy of the Nuclear Regulatory Committee (NRC)-state-approved license or agreement shall be submitted. If no such material is to be used, it should be so stated.

6. Recombinant DNA

Research involving recombinant DNA must meet or exceed NIH Guidelines for Research Involving Recombinant DNA Molecules, January 1997 edition. Include a written approval letter from the organization’s Institutional

Biosafety Committee (IBC). The IBC reviews all applications to perform protocols involving recombinant DNA (biohazardous material). If not applicable, it should be so stated.

Copies of the NIH Guidelines are available at:
Fax: (301) 496-9839
Phone: (301) 496-9838
E-mail: www.nih.gov/od/orda
Mail: Office of Recombinant DNA Activities
National Institutes of Health, MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda, MD 20892-7010

7. Biological Defense Program Requirements

Contractors performing work with Biosafety Level-3 and 4 material must prepare a safety plan in accordance with 32 CFR 626.18.

Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of Biological Defense Program (BDP) activities and the appropriate support necessary, to include any equipment and training to provide effective emergency response. Agreements with external agencies must be formalized. (For the purpose of this requirement, the term "local emergency support agencies" refers to any agency that could reasonably be expected to have some capability to provide timely and effective support in the management or resolution of a biological mishap arising from BDP operations.) A copy of this agreement must be submitted
with the proposal.

(Sample)

Local Emergency Support

(Police, Fire, Health Department), is fully aware of the research program entitled _____in the Department of _____at _____, which is supported by the U.S. Army Medical Research and Materiel Command (Contract Number_____). In the event that a situation requires our response, we are equipped and prepared to handle those emergencies as appropriate for this project.

Acknowledged:

_____ _____ _____
Name Title (e.g., Fire Chief) Date

The PI is directly responsible and liable for all aspects of research project safety and ensures that all Facility Safety Plan requirements are in compliance with 32 CFR 626 and 627 (Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements).

USAMRAA 52.027-4004 SAFEGUARDING PROPRIETARY INFORMATION (MAY 1999) (USAMRAA)

a. "Proprietary information" shall mean all information, whether disclosed orally, in writings, by drawings, or otherwise relating to the work to be performed under this contract, whether proprietary to the Government or one of its collaborating partners. Proprietary information includes, but is not limited to, information regarding properties, formulae, structures, manufacturing processes, and test results. Information ceases to be proprietary when it is generally available to the public or is available from sources other than the Department of the Army. All information submitted to the contractor under this contract shall be presumed to be proprietary to the Department of the Army or one of its collaborating partners until the Department of the Army announces to the contrary.

b. The contractor shall safeguard proprietary information both during and after the term of this contract, and shall neither appropriate, nor disclose, nor make unauthorized use of the proprietary information received under this contract. The requirements of this paragraph include, but are not limited to, the following:

(1) Maintenance of a high degree of physical security over proprietary information at all times;
(2) Discussion of proprietary information only among contractor's employees whose duties and responsibilities require knowledge of that information; and,
(3) Elimination of proprietary information in open publications by the contractor and its personnel.

c. The contractor shall require all personnel who receive proprietary information to execute the statement in paragraph d below when this contract becomes effective or when first employed (if employed after the contract becomes effective). All statements executed pursuant to this paragraph shall be forwarded to the U.S. Army Medical Research Acquisition Activity when this contract terminates, when the employment ends, or upon request of the Contracting Officer.

d. The following statement shall be executed pursuant to paragraph c above:

I hereby acknowledge that I have been informed that my duties may require that I have access to proprietary information. I understand this proprietary information which I will receive includes, but is not limited to, properties, formulae, structures, protocols, manufacturing processes, and test results.

I agree that I will neither appropriate nor disclose nor make unauthorized use of proprietary information both during and after my employment. I further agree that I will neither include nor draw upon proprietary information received under this contract in open publication. This agreement is executed with the intention that collaborating partners of the United States Government who have submitted information to the Government under non-disclosure obligations shall be third party beneficiary hereunder, and shall have the right to enforce the obligations undertaken herein.

Name:
Date:

e. The contractor shall insert the substance of paragraphs a through d above in each subcontract hereunder. Compliance with the provisions of this clause shall be the responsibility of the contractor.

USAMRAA 52.028-4002 **INSURANCE (MAR 1999) (USAMRAA)**

Prior to award of this contract, the contractor shall obtain and provide proof of insurance in the types and amounts specified in FAR 28.307-2 except as noted.

USAMRAA 52.032-4004 **INVOICES – CONSTRUCTION (MAR 1999) (USAMRAA)**

Invoices will be submitted to the following address:

Directorate of Installation Services
ATTN:
201 Beasley Drive
Fort Detrick MD 21702-5035

USAMRAA 52.032-4005 **INCREMENTAL FUNDING (MAR 1999) (USAMRAA)**

a. It is estimated that the total cost to the Government for the full performance of this contract for the period to will be $ There have been funds allotted for reimbursement of allowable costs, and applicable fee, incurred in the performance of this contract in the amount of only $. It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period to . The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:
Amount On or about

$

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.

USAMRAA 52.032-4011 **VOUCHERS (MAR 1999) (USAMRAA)**

a. The Contractor shall submit an original and one copy of public vouchers (SF 1034) not less frequently than monthly to for review and forwarding for payment.
b. Voucher categories shall adhere to budget categories listed in the negotiated budget used for funding the contract. All vouchers shall state the total amount claimed and the subtotals claimed in the following types of categories: salaries and wages, overhead stating percentage and base, travel, equipment, supplies, and any other categories used in the negotiated budget. Suitable detailed support for amounts claimed shall be shown on continuation sheets. For instance, direct labor costs should include number of hours worked by individual, hourly rate, and total. Travel costs should include number of trips, public carrier rates, per diem costs, incidental costs, etc.
c. Cumulative totals of expenditures in each category shall also be shown.
d. Each voucher submitted must state the period of performance. Each voucher submitted must request payment for only those man-hours or cost expenditures incurred in that period.
e. The Contracting Officer shall be notified immediately in the event a budget category is expected to deviate from the negotiated budget.
f. The completion voucher shall be submitted by the Contractor to the Contracting Officer.

USAMRAA 52.032-4011 ALT I **VOUCHERS – ALTERNATE I (MAR 1999) (USAMRAA)**

a. The Contractor shall submit an original and one copy of public vouchers (SF 1034) not less frequently than monthly to for review and forwarding for payment.
b. Voucher categories shall adhere to budget categories listed in the negotiated budget used for funding the contract. All vouchers shall state the total amount claimed and the subtotals claimed in the following types of categories: salaries and wages, overhead stating percentage and base, travel, equipment, supplies, and any other categories used in the negotiated budget. Suitable detailed support for amounts claimed shall be shown on continuation sheets. For instance, direct labor costs should include number of hours worked by individual, hourly rate, and total. Travel costs should include number of trips, public carrier rates, per diem costs, incidental costs, etc.
c. Cumulative totals of expenditures in each category shall also be shown.
d. Each voucher submitted must state the period of performance. Each voucher submitted must request payment for only those man-hours or cost expenditures incurred in that period.
e. The Contracting Officer shall be notified immediately in the event a budget category is expected to deviate from the negotiated budget.
f. The completion voucher shall be submitted by the Contractor to the cognizant audit agency (if applicable) for audit review and forwarding to the Contracting Officer. Simultaneously, the Contractor shall submit a courtesy copy of this voucher to the Contracting Officer.
g. To assure expenditures for research contracts are proper and in accordance with the research agreement documents and approved project budgets, the final voucher requesting payment under this contract shall include a certification which reads essentially as follows:
I certify that all expenditures reported (or payments requested) are for appropriate purposes and in accordance with the agreements set forth in the application and award documents.

_____
(Signed by an Authorized Official of the Organization)

USAMRAA 52.035-4002 **PRINCIPAL INVESTIGATOR (MAR 1999) (USAMRAA)**

The Principal Investigator for this contract is . This individual shall be continuously responsible for the conduct of the research project. The contractor shall obtain the Contracting Officer's approval to change the Principal Investigator or to continue the research work during a continuous period in excess of three months without the participation of an approved Principal Investigator. This contract is based on the Principal Investigator devoting of effort to the project over the term of the contract. The contractor shall advise the Contracting Officer if the Principal Investigator will, or plans to, devote substantially less effort to the work than estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

USAMRAA 52.035-4005 USE OF LABORATORY ANIMALS (OCONUS) (NOV 2000)(USAMRAA)

All laws, customs, and practices of the country in which the research is to be conducted shall be complied with insofar as use of laboratory animals is concerned. In those instances where the local laws and regulations are in conflict with the laws and regulations of the United States and the Department of Agriculture, the more humane and stringent will be followed. The following U.S. standards and regulations for the protection, treatment, and use of animals should be adhered to where practicable: 7 U.S. Code 2131 et. Seq. and 9 Code of Federal Regulations, Subchapter A, Parts 1-4.

USAMRAA 52.035-4011 **GOOD LABORATORY PRACTICES (MAR 1999) (USAMRAA)**

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract, grant, or cooperative agreement. In addition to the FDA representative, the Contracting Officer's Representative (COR) or Grant Officer's Representative (GOR) shall have access to the contractor's records and specimens. With reference to paragraph 58,195(g) of the GLP regulations, the contractor shall notify the COR/GOR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58,195. On expiration or termination of the contract, the contractor shall notify the COR/GOR of any remaining unused test articles.

USAMRAA 52.035-4011 ALT I **GOOD LABORATORY PRACTICES – ALTERNATE I (MAR 1999) (USAMRAA)**

a. The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract, grant, or cooperative agreement. In addition to the FDA representative, the Contracting Officer's Representative (COR) or Grant Officer's Representative (GOR) shall have access to the contractor's records and specimens. With reference to paragraph 58,195(g) of the GLP regulations, the contractor shall notify the COR/GOR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58,195. On expiration or termination of the contract, the contractor shall notify the COR/GOR of any remaining unused test articles.

b. The studies on health effects, environmental effects, and chemical fate testing required by this contract shall comply with the GOOD LABORATORY PRACTICE STANDARDS regulations. These regulations should assure the quality and integrity of data submitted pursuant to Section 4(a) of the Toxic Substances Control Act. The contractor shall notify the Contracting Officer by telephone immediately upon announcement by a representative of the Environmental Protection Agency (EPA) of an inspection of studies performed under this contract. In addition to the EPA
representative, the Contracting Officer's Representative shall have access to all experimental and contractual records. Archiving of test articles, records, tissues and specimens is the responsibility of the contractor.

USAMRAA 52.035-4012 **CURRENT GOOD MANUFACTURING PRACTICES (MAR 1999) (USAMRAA)**

The drug or biological drug products required by this contract, grant, or cooperative agreement shall be developed and produced in compliance with the CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FOR FINISHED PHARMACEUTICALS regulations for parenteral products, 21 CFR, Part 211. Results of routine FDA inspections for licensed facilities as recorded on Form FDA 482 shall be supplied to the Contracting Officer's Representative or Grant Officer's Representative and become part of the contract file.

USAMRAA 52.035.4020 **USE OF TECHNICAL REFERENCE FACILITY (MAR 1999) (USAMRAA)**

The contractor agrees to use**,** to the extent practical**,** the technical reference facilities of the Defense Technical Information Center, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218 for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources, whether or not Government controlled, shall be consulted for the same purpose.

USAMRAA 52.035-4022 **INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999) (USAMRAA)**

a. "Misconduct" or "Misconduct in Science" is defined as
fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.
c. The contractor agrees to:
(1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
(2) Comply with its own administrative process;
(3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
(4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
(5) Report to the Administrative Contracting Officer (ACO)
a decision to initiate an investigation into possible scientific misconduct.
d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:
(1) An immediate health hazard is involved;
(2) There is an immediate need to protect Federal funds or
equipment;
(3) A probability exists that the alleged incident will be
reported publicly; or
(4) There is a reasonable indication of possible criminal
violation.

USAMRAA 52.035-4024 **EMERGENCY COORDINATION AND REPORTING (BDRP) (MAR 1999) (USAMRAA)**

a. The contractor shall review the Emergency Response Plan/Safety Program Plan annually, during the month of July, in consultation with each participating external support agency. The Emergency Response Plan shall be formally revised, where necessary, to incorporate current emergency support requirements. The revised Emergency Response Plan (with the agreements for emergency support as appendices) shall be formalized in writing. A copy of the revision shall be retained in your organizational safety office.
b. The contractor shall submit a letter report documenting the outcome of the annual review of its Emergency Response Plan. The report shall include the dates of the annual review and coordination, and shall identify and describe all provisions that represent changes to the initial Emergency Response Plan or the previous year's annual report. The report shall be submitted no later than August 1 of each year, beginning with the first August during the performance of your contract.
c. All reports identified in this provision shall be submitted to the following address:
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-S
504 Scott Street
Fort Detrick, Maryland 21702-5012

USAMRAA 52.035-4028 **ETIOLOGIC AGENTS--BIOLOGICAL DEFENSE RESEARCH PROGRAM (MAR 1999) (USAMRAA)**

a. For purpose of this contract etiologic agent--biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 723 of the Department of Health and Human Services regulations, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the U.S. Army as a threat agent. The contractor shall comply with the following when working with etiologic agents:

1. 29 Code of Federal Regulations 1910
2. Occupational Health Standards, and the U.S. Department of Health and Human Services (DHHS)
3. DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 1993, as amended
4. 32 CFR 626 Biological Defense Safety Program
5. 32 CFR 627 Biological Defense Safety Program

b. Etiologic agents shall be packaged, labeled, shipped, and transported in accordance with applicable Federal, state and local laws and regulations, to include:

1. 42 CFR 72 (Interstate Shipment of Etiologic Agents)
2. 49 CFR 172 and 173 (Department of Transportation)
3. 9 CFR 122 (USDA Restricted Animal Pathogens)
4. International Air Transport Association Dangerous Goods Regulations.
5. The United States Postal Service shall not be used for transportation of BDRP activities involving etiologic agents.

USAMRAA 52.035-4028 ALT I **ETIOLOGIC AGENTS--BIOLOGICAL DEFENSE RESEARCH PROGRAM – ALTERNATE I (MAR 1999) (USAMRAA)**

a. For purpose of this contract etiologic agent--biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 723 of the Department of Health and Human Services regulations, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the U.S. Army as a threat agent. The contractor shall comply with the following when working with etiologic agents:

1. 29 Code of Federal Regulations 1910
2. Occupational Health Standards, and the U.S. Department of Health and Human Services (DHHS)
3. DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 1993, as amended
4. 32 CFR 626 Biological Defense Safety Program
5. 32 CFR 627 Biological Defense Safety Program
6. Any additional procedures required by the nation where the work is to be performed.

b. Etiologic agents shall be packaged, labeled, shipped, and transported in accordance with applicable Federal, state and local laws and regulations, to include:

1. 42 CFR 72 (Interstate Shipment of Etiologic Agents)
2. 49 CFR 172 and 173 (Department of Transportation)
3. 9 CFR 122 (USDA Restricted Animal Pathogens)
4. International Air Transport Association Dangerous Goods Regulations.
5. The United States Postal Service shall not be used for transportation of BDRP activities involving etiologic agents.

USAMRAA 52.035-4029 **CONTRACTOR SAFETY AND REPORTING (BDRP) (MAR 1999) (USAMRAA)**

a. The contractor shall operate under established safety
programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. These safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.
b. The contractor shall conduct this contract work under
established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.
c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.
1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Government designated Biosafety Officer
Quarterly	First line supervisor
Annual	Contractor safety personnel

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	First line supervisor
Annual	Government designated Biosafety Officer

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	First line supervisor
Semiannual	Government designated Biosafety Officer

4. Copies of all biosafety inspection reports will be
distributed as follows:
Original:
In the contractor's records (Retained for at least three years)
One copy to the following:
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-S
504 Scott Street
Fort Detrick, Maryland 21702-5012
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLD
504 Scott Street
Fort Detrick, Maryland 21702-5012
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA
820 Chandler Street
Fort Detrick, Maryland 21702-5014

USAMRAA 52.035-4030 **CONTRACTOR SAFETY AND REPORTING (NON-BDRP) (MAR 1999) (USAMRAA)**

a. The contractor shall operate under established safety programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. These safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.

b. The contractor shall conduct this contract work under established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.

c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.

1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Contractor
Quarterly	First line supervisor
Annual	Contractor safety personnel

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	First line supervisor
Aannual	Government designated Biosafety Officer

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	First line supervisor
Semiannual	Government designated Biosafety Officer

4. Copies of all biosafety inspection reports will be distributed as follows:

Original:
In the contractor's records
One copy to the following:
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-S
504 Scott Street
Fort Detrick, Maryland 21702-5012
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLA
504 Scott Street
Fort Detrick, Maryland 21702-5012
U.S. Army Medical Research Aquisition Activity
ATTN: MCMR-AAA
820 Chandler Street
Fort Detrick, Maryland 21702-5014

USAMRAA 52.035-4031 PROHIBITION OF USE OF HUMAN SUBJECTS (MAR 2000) (USAMRAA)

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of human subjects in any manner whatsoever. In the performance of this award, the recipient agrees not to come into contact with, use or employ, or subcontract for the use or employ of any human subjects for research, experimentation, tests or other treatment under the scope of work as set out in the award

USAMRAA 52.035-4032 USE OF HUMAN SUBJECTS (MAR 29 2000) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving humans as research subjects for the following protocols:

Protocols not identified are not approved.

b. The contractor and subcontractors are required to submit documentation of IRB review of protocols and consent forms from each of the funded institutions. Research at funded institutions may not begin until the U.S. Army Surgeon General's Human Subjects Research Review Board approves the protocol and consent form for that site.

c. The contractor and subcontractors who enroll additional unfunded institutions are responsible to ensure that the institute conducts research in accordance with 45 CFR 46 and other applicable federal and state regulations. Prior to inclusion of any unfunded institution's participation under this award, the recipient is responsible to notify the Grants Officer.

d. Volunteer Registry Data Sheet (USAMRDC Form 60-R). In accordance with the "Use of Human Subjects" provision above, the Volunteer Registry Data Sheet, USAMRDC Form 60-R (Attachment _), is to be completed at the time the subject consents to participate and is entered into the study. The form shall be submitted to the Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012 upon completion of the research project or upon expiration/termination of the award, whichever occurs first.

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USAMRAA 52.035-4033 **USE OF ANATOMICAL SUBSTANCES (MAR 1999) (USAMRAA)**

1. The contractor, or its subcontractors, shall not conduct any research under this contract involving human anatomical substances, until all of the following conditions are met:
a. The research protocol(s) has been reviewed and approved
by an appropriate institutional review board or committee;
b. The approved research protocol(s) has then been forwarded to: Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, Fort Detrick, MD 21702-5012. The protocol(s) must be reviewed and approved by the USAMRMC Duty Chief of Staff for Regulatory Compliance and Quality, Human Use Review and Regulatory Affairs Division; and,
c. The contractor has received written approval from the
contracting officer.
2. Any anatomical substance (organs, tissues, or tissue fluids) linked by identifiers to a particular person and used for research under this contract shall be donated for the purpose of research or investigation. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and shall relinquish all ownership and/or rights to the substance. All human anatomical substance used in research under this contract shall be lawfully acquired. It should be noted that a general autopsy consent form or a consent to perform surgery in and of themselves, may not be adequate. If excised or autopsy tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.

USAMRAA 52.035-4034 **POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS (NOV 2000)(USAMRAA)**

Contract post-award oversight of the use of laboratory animals shall be the responsibility of the contractor's Animal Care and Use Committee (ACUC). The Principal Investigator shall notify the Contracting Officer in writing of any significant changes to the proposed use of animals, which was the basis for contract award. These changes must be approved by the contractor's ACUC and the U.S. Army Medical Research and Materiel Command. In addition, the ACUC shall immediately notify the Contracting Officer of any violations of law or regulation involving animal care, or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

USAMRAA 52.035-4035 USE OF LABORATORY ANIMALS ANNUAL REPORTING (CONUS)(NOV 2000) (USAMRAA)

a. **The contractor shall annually prepare and** electronically **submit the U.S. Army Medical Research and Materiel Command Animal Use Report (SEE DFARS 252.235-7002) detailing the use of animals in the research and development sponsored by the Army. The website containing information for electronic submission of this report may be found at http://www-usamraa.army.mil.**

b. **A letter with additional instructions concerning use of the electronic website will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U.S. Army Medical Research and Materiel Command no** later than 1 December of that year.

c. **For contracts with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at http://www-usamraa.army.mil.**

d. **The contractor shall also furnish a copy of the most recent USDA Inspection Report. This report shall be submitted via fax or mailed to:**

Commander
U.S. Army Medical Research & Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012
FAX: (301) 619-4165

e. The contractor is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report and USDA Inspection Report be submitted for any subcontract facility.

USAMRAA 52.035-4036 ANNUAL ANIMAL USE REPORTING (OCONUS)(NOV 2000) (USAMRAA)

a. **The contractor shall annually prepare and** electronically **submit the U.S. Army Medical Research and Materiel Command Animal Use Report (SEE DFARS 252.235-7002) detailing the use of animals in the research and development sponsored by the Army. The website containing information for electronic submission of this report may be found at http://www-usamraa.army.mil .**

b. **A letter, with additional instructions concerning use of the electronic website, will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U.S. Army Medical Research and Materiel Command no** later than 1 December of that year.

c. **For contracts with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at http://www-usamraa.army.mil.**

d. **The contractor is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report be submitted for any subcontract facility.**

USAMRAA 52.036-4002 **ESTIMATED COST OF PROPOSED WORK (MAR 1999) (USAMRAA)**

The estimated cost of the proposed procurement is between
$ and $.

USAMRAA 52.042-4025 **REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (MAR 1999) (USAMRAA)**

a. Contractors are encouraged to publish results of research supported by USAMRMC in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.

b. Manuscripts intended for publication in any media shall
be submitted to the COR, simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the COR, even though publication may be subsequent to the expiration of the contract.

c. The contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings prior to public release. This is not intended to restrict dissemination of research information but to allow the U.S. Army Medical Research and Materiel Command (USAMRMC) advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(1) "This work is supported by the U.S. Army Medical Research and Materiel Command under Contract No. DAMD17- - - ."
(2) "The views, opinions and/or findings contained in
this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."
(3) "In conducting research using animals, the
investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985)."
(4) "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by 45 CFR 46 and 32 CFR 219 (Protection of Human Subjects)."
(5) In conducting work involving the use of recombinant DNA the investigator(s) adhered to Guidelines for Research Involving Recombinant DNA Molecules; Notice, Federal Register, July 5, 1994, Volume 59, Number 127.

USAMRAA 52.042-4028 **TRAVEL (AUG 2000) (USAMRAA)**

a. Approval of Foreign Travel. The cost of foreign travel is allowable only when the specific written approval of the Contracting Officer or Contract Specialist responsible for administration of the contract is obtained prior to commencing the trip. Approval must be requested at least 30 days before the scheduled departure date in order that all necessary clearances may be processed. Each individual trip must be approved separately even though it may have been included in a previously approved budget. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions.
b. Domestic/local travel shall take place in accordance with Department of Defense Joint Travel Regulations (JTR). Documentation showing dates and mileage for such travel shall be maintained and furnished in support of invoice claiming reimbursement.

USAMRAA 52.042-4033 **KEY PERSONNEL (MAR 1999) (USAMRAA)**

a. The Contractor agrees to utilize the following Key Personnel on this contract:

b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.
c. The offerer must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation should include but not be limited to: name, curriculum vitae, type and description of experience.
d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.
e. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.
f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

USAMRAA 52.045-4003 **GOVERNMENT-FURNISHED DRUGS/COMPOUNDS (MAR 1999) (USAMRAA)**

Candidate drugs/compounds shall be provided by . The types, amounts, and delivery schedule of candidate drugs/compounds provided will be determined by the Contracting Officer's Representative (COR). It is anticipated that approximately number of drugs/compounds will be furnished.

USAMRAA 52.045-4008 **GOVERNMENT-FURNISHED PROPERTY/ MATERIEL (MAR 1999) (USAMRAA)**

a. Pursuant to the Government Property Clause set forth in the General Provisions of this contract, the Government shall furnish F.O.B. contractor's place of performance, the Government-owned property/materiel listed in paragraph "d" below for use in the performance of this contract.

b. The items shall be delivered in accordance with the schedule set forth in paragraph "d" below.

c. If the items are not received in accordance with the schedule set forth in "d" below, the contractor shall immediately notify the Contracting Officer in writing.

d. Government-furnished property/materiel delivery schedule:

Description Estimated Quantity Time of Delivery

USAMRAA 52.045-4008 ALT I **GOVERNMENT-FURNISHED PROPERTY/ MATERIEL – Alternate I (MAR 1999) (USAMRAA)**

The dilute chemical surety materiel and Mark I kits required for the performance of this contract shall be provided by the U.S. Army on an as needed basis and shall be coordinated between the contractor and the Contracting Officer. No work shall be performed using dilute chemical surety materiel prior to Government written approval of the contractor's Facility Safety and Surety Plan.

a. Pursuant to the Government Property Clause set forth in the General Provisions of this contract, the Government shall furnish F.O.B. contractor's place of performance, the Government-owned property/materiel listed in paragraph "d" below for use in the performance of this contract.

b. The items shall be delivered in accordance with the schedule set forth in paragraph "d" below.

c. If the items are not received in accordance with the schedule set forth in "d" below, the contractor shall immediately notify the Contracting Officer in writing.

d. Government-furnished property/materiel delivery schedule:

Description	Estimated Quantity	Time of Delivery
Government Provided Mark I Kits	To Be Determined	As Required
Government Provided Storage Freezer Lock	To Be Determined	As Required

USAMRAA 52.045-4010 **PROPERTY ADMINISTRATOR (MAR 1999) (USAMRAA)**

The designated property administrator for Government property acquired for use under this contract is .

USAMRAA 52.045-4020 **PROPERTY REPORTING (COMMERCIAL) (MAR 1999) (USAMRAA)**

The designated property administrator for Government property acquired for use under this contract is the Contract Specialist, US Army Medical Research Acquisition Activity, Fort Detrick, MD 21702-5014. The contractor shall furnish the designated property administrator report, (i.e. DD FORM 1662, DOD Property in the Custody of Contractors).

a. Interim Inventories - Annually, as of 30 September, report due 10 October, each year.
b. Final Inventory - When the contract expires.